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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/791,974 | 03/03/2004 | Ray L. Pickup | 10004227-9 | 4848 |

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HEWLETT-PACKARD COMPANY
Intellectual Property Administration
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EXAMINER

HAND, MELANIE JO

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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3761

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/791,974 | Applicant(s) PICKUP ET AL. | |
| | Examiner Melanie J. Hand | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-100, 102-109, 118-136, 140, 141 and 145-150 is/are pending in the application.
 4a) Of the above claim(s) 55-82, 134, 135 and 145-147 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83-100, 102-109, 118-133, 136, 140, 141 and 148-150 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the invention of Group III, claims 83-100, 102-109, 118-133, 136, 140, 141 and 148-150 in the reply filed on December 5, 2005 is acknowledged. Claims 55-82, 134, 135, 145, 146 and 147 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Examiner acknowledges that claims 1-28, 30-54, 101, 110-117, 137-139, and 142-144 had been cancelled by applicant in a preliminary amendment filed March 3, 2004 prior to the mailing of the restriction requirement on November 8, 2005 and therefore were not pending at the time of the restriction requirement.

Priority

Acknowledgment is made of applicant's claim for priority as a divisional of copending Application No. 09/967,603 filed on September 28, 2001 and issued as Patent No. 6,723,077.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 23, 2004 was filed after the mailing date of the Application on March 3, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 150 is objected to because of the following informalities: The claim language appears to end after “comprising” without setting forth limitations that further limit the parent claim. As a result, Claim 150 cannot be examined on its merits in this Office action. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 121, 122, 129, 130 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a drug delivery device that monitors physiological parameters and uses resulting data to administer appropriate dosages of a drug, does not reasonably provide enablement for a device that can autonomously determine what particular activity a user is engaged in and subsequently discern an appropriate dosage level that is different from another activity that produces an identical physiological response. For example, the physical activity of running produces a substantially identical physiological response to climbing a hill, e.g. more rapid heartbeat and more rapid breathing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Applicant is asked to either provide satisfactory evidence that the claimed invention is capable of autonomously discerning such external input or amend the claim so as to be consistent in scope with the disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 91, 105-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "ink jet technology" (claim 91), "thermal ink jet technology" (claim 105), "piezoelectric ink jet technology" (claim 106) and "electrostatic actuated inkjet technology" (claim 107) do not clearly and sufficiently describe the structural features and steps of the method. By referring to a technology in general, applicant is not sufficiently describing which aspects of the particular technology are incorporated and how they are incorporated in the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 83-100, 108, 109, 111-122, 126-130, 136, 140, 141, and 148-150 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobsen et al (U.S. Patent No. 5,860,957).

With respect to **Claims 83,88,91,98,148**: Jacobsen teaches administering a drug cutaneously via a multipathway drug delivery device 20 comprising a fluid jet delivery pod 510 and drug

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containment pouch 506. (Col. 11, lines 50-52) The drug is expelled through aperture 522. (Col. 12, lines 1-5) Jacobsen teaches that the device is capable of administering daily delivery of a drug composition (Col. 5, lines 27-29), therefore the device is intended for prolonged contact with a cutaneous surface and capable of repeatedly dispensing a drug composition.

With respect to **Claim 84**: Jacobsen teaches that drug delivery device 20 is a patch. (Col. 5, lines 13-16)

With respect to **Claims 85,86,149**: Jacobsen teaches that device 20 has double-sided adhesion to prevent movement on a cutaneous surface after said patch 20 is applied, after which application, said device 20 is operatively connected to control pad 10 by communication cable 30 which actuates a drug administration program. (Col. 5, lines 13-55) Device 20 is encased in a foil wrapper prior to use, and Examiner asserts that this wrapper is capable of being reused to cover patch 20 again after a drug has been delivered to the absorbent sponge material in the patch to retain any drug composition amount present in said sponge material. (Col. 5, lines 55-61)

With respect to **Claim 87**: Bottom cap 536 seals pod 512 shut. Aperture 538 extends through the bottom cap for access by a hypodermic needle. A needle guard and seal 540 are positioned beneath the bottom cap and function to keep the needle end sealed and sterile until the seal is punctured upon a first propellant charge 526 actuated by control pad 10 for drug delivery from pouch 506. (Col. 12, lines 16-22, 31-48) Since the drug containment pouch 506 is disposed within pod 512, it is in prolonged contact with seal 540.

With respect to **Claim 89,90,99,100**: Since Jacobsen teaches a pouch as a drug container and said pouch is collapsible and loose, the drug supply via pouch 506 is replenishable by supplying a new pouch 506 and placing said pouch with a predetermined unit dosage in said pod 512.

With respect to **Claim 92,93**: Jacobsen teaches that control pad 10 allows the user to program various frequencies of drug delivery, including dosages that enabled sustained levels of a drug through a maintenance delivery sequence and dosages administered at intervals. (Col. 5, lines 24-32, Col. 6, lines 45-50)

With respect to **Claim 94**: Jacobsen teaches that device 20 is capable of storing and mixing two separate drug composition components prior to delivery to a cutaneous surface. (Col. 13, lines 54-62)

With respect to **Claim 95,96**: Jacobsen teaches pod 580 having a first chamber 582 that is half full of a first drug component to be mixed with a second component. Said second drug component is stored in a second chamber 584 until it is ejected through a one-way valve 596 (interpreted herein as an orifice) to said first chamber 582 wherein it is mixed with said first component and the resulting composition is then capable of being delivered through patch 20. (Col. 13, lines 54-66, Col. 14, lines 1,2)

With respect to **Claim 97**: Since Jacobsen teaches that delivery device 20 is a patch and a drug delivery pod 580 capable of mixing two components of the same of different phases, Jacobsen is teaching that the component mixing is capable of occurring within a patch 20.

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With respect to **Claim 108,109,118,126**: Jacobsen teaches that a drug is specifically selected by name via the ability of device 20 to read a label on a drug storage container as it is inserted. An external host interface 48 obtains and stores data via a wireless infrared reading device from a computer having microprocessor 40, said data including user ID, drug ID, dose and usage information. Wireless interface 48 then uses said data to monitor a patient's physiological status in tandem with sensors, this circuit also thus being capable of responding to the data by administering the appropriate dosage via device 20 according to the stored schedule data. (Col. 7, lines 24-38)

With respect to **Claim 119-122,127,128,129,130**: Please see the rejection of claim 108 in addition to the following: Jacobsen teaches using device 20 having interface 48 to administer stimulants, which would require monitoring of a patient's heartbeat and breathing (directly correlated to a change in activity level) as physiological parameters in order to function properly. (Col. 6, lines 32-35) This rejection of claims 121,122,129,130 is taking into account the rejection of those claims under 35 U.S.C 112.

With respect to **Claim 140,141**: Jacobsen teaches that control pad 10 is responsible for sending electrical current to ignition wiring, which then ignites propellant gas, which expands the drug containment pouch so as to propel the drug in a gaseous state as a stream of droplets through nozzle 460 for delivery into the user's skin. Control pad 10 comprises a keypad 42 that is adapted for receiving input in the form of keystrokes from a user, which defines a manual triggering of control pad 10, the actuation device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 123-125 and 131-133 rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (U.S. Patent No. 5,860,957).

With respect to **Claims 123-125, 131-133**: Jacobsen teaches a plurality of sensors 60 for providing feedback regarding a patient's physiological status. Jacobsen does not teach any particular type of sensor, however since the sensor's detect a state of fatigue in the user (decreasing heartbeat and breathing rates) ('957, Col. 6, lines 44-46), it would be obvious to one of ordinary skill in the art to employ accelerometers as sensors 60 as an accelerometer measures its own acceleration and can thus be used as a reference baseline for the calculation of the user's heartbeat and breathing rates.

Claims 102-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al ('957) in view of Hayes et al (U.S. Patent No. 6,325,475).

With respect to **Claims 102-107**: Jacobsen teaches a fluid jet dispenser 450 but does not teach a particular type of fluid jet dispenser. Hayes teaches a jet dispenser for administering airborne materials into a user's nose that utilizes ink-jet technology. Hayes teaches that the transducer in the ink jet device can be piezoelectric or electromechanical, which encompasses thermal and silicon electrostatic transducers. ('475, Col. 7, lines 29-37) Since Hayes teaches that these are equivalent and all are suitable for use in an inkjet drug delivery device, it would be obvious to one of ordinary skill in the art to utilize any of piezoelectric, thermal or silicon electrostatic transducers as taught by Hayes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

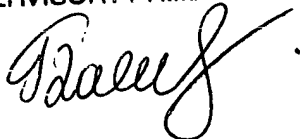
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', with a long, sweeping horizontal stroke extending to the right.